IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CIPLA LTD., Plaintiff, v. SUNOVION PHARMACEUTICALS INC., Defendant.	C.A. No. 1:15-cv-00424-LPS [redacted] **PUBLIC - REDACTED VERSION**

OPENING BRIEF IN SUPPORT OF PLAINTIFF CIPLA LTD.'S MOTION TO EXCLUDE EXPERT TESTIMONY

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NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff Cipla Ltd. ("Cipla") has filed various claims in this case against Defendant Sunovion Pharmaceuticals Inc. ("Sunovion") alleging infringement of Cipla's U.S. Patent No. RE 43,984 (the "RE '984 Patent"). (D.I. 200). Both fact discovery and expert discovery are now closed. (*See* D.I. 255). A five-day jury trial is set to begin on May 21, 2018. (D.I. 178).

SUMMARY OF THE ARGUMENT

Cipla moves to exclude respective testimony of four Sunovion expert witnesses: Mr. Thomas Hoxie, Esq.; Ms. Samantha Miller; Mr. Robert L. Vigil, Ph.D.; and Dr. Leonard Chyall.

Mr. Hoxie's testimony should be excluded outright under *Daubert*. Mr. Hoxie is not qualified to testify as an expert on Patent Office practice and procedure, and even if he were, the opinions he intends to offer are not insight into Patent Office procedure that would aid a trier of fact—they are improper *legal conclusions*. Additionally, he also has no expertise on statutory interpretation, FDA submissions, or technical expertise on the underlying subject matter in this case to state when and how Sunovion made "prior commercial use" of levalbuterol tartrate. Mr. Hoxie's impermissible legal and technical opinions are the kind that the Court routinely strikes.

The testimony of Ms. Miller relating to royalty rates applicable in this case should be excluded pursuant to Federal Rule of Evidence 702. Ms. Miller's opinions are based exclusively on her own personal experience negotiating licensing deals in the pharmaceutical industry—but Ms. Miller has failed to provide any facts underlying her opinion. Without these details, Ms. Miller's opinions "cannot reasonably be assessed for reliability" or "challenged in some objective sense," as required under *Daubert* and Federal Rule of Evidence 702.

With respect to Mr. Vigil, at his deposition, he introduced for the *first time* a *new* opinion regarding Sunovion's policy with respect to [redacted]. Mr.

Vigil concedes that this new opinion does not appear anywhere in his expert report. Indeed, the basis for Mr. Vigil's opinion was only formed [redacted] *the day before Mr. Vigil's deposition*. As such, Mr. Vigil's new opinion should be excluded under Federal Rule of Civil Procedure 37(c)(1).

Finally, Dr. Chyall's opinions should be excluded outright as a contradiction to the Court's claim construction. Dr. Chyall's opinion with respect the reverse doctrine of equivalents is based on his conclusion that [redacted]. During claim construction, however, the Court expressly *rejected* multiple attempts by Sunovion to import method (or process) limitations into the asserted *product* claims of the RE '984 Patent. As such, Dr. Chyall's opinion is nothing more than a restatement of Sunovion's unsuccessful claim construction arguments under the new guise of the "rarely applied" reverse doctrine of equivalents, and should thereby be excluded.

STATEMENT OF RELEVANT FACTS

A. Sunovion Expert Witness Mr. Thomas Hoxie, Esq.

Mr. Hoxie claims he is an expert in Patent Office practice and procedure, yet Mr. Hoxie has never served as a patent examiner, nor held any other role in the Patent Office. *See* Declaration of Joshua H. Lee ("Lee Decl."), Ex. D, at 151:10–16; 161:5–19; *see also* Lee Decl., Ex. A, at ¶¶ 8–18 & Exhibit 1 (Mr. Hoxie's CV). Moreover, although Mr. Hoxie has prosecuted patent applications, he could only identify one reissue application that involved rejections for recapture, and he characterized that application as a "[redacted]" Lee Decl., Ex. D, at 170:7–15, 170:22–171:2. Nevertheless, his reports are directed to *legal conclusions* with respect to Patent Office practice and procedure and other legal issues, including the validity of the RE '984 Patent under 35 U.S.C. § 251, § 102(g), and § 112, and priority under § 119. *See, e.g.*, Lee

Decl., Ex. A, at ¶¶ 100–128; Ex. B, at ¶¶ 11–18, 22–26, 35, 43, 45; Ex. C, at ¶¶ 10–29, 63–99.[1] Appendix A hereto provides enough specific examples to support exclusion of Mr. Hoxie's testimony in the case altogether.

Mr. Hoxie is also not a technical expert. Mr. Hoxie admittedly lacks experience in the relevant art and is not a person of ordinary skill in the art under any proffered definition. *See, e.g.*, Lee Decl., Ex. D, at 165:19–166:24. Nevertheless, Mr. Hoxie sets forth opinions on Sunovion laboratory notebooks and other technical documents in addressing the pure legal issue of statutory interpretation of 35 U.S.C.§ 273 with respect to Sunovion's prior commercial use defense. For example, [redacted] Lee Decl., Ex. B, at ¶ 35; *see also id.* at ¶¶ 28–34, 36–40, 42–43. [redacted] *Id.* at ¶¶ 38–44 & n.9. Assumptions about the results of chemistry experiments, and the properties of their products are beyond Mr. Hoxie's scientific qualifications.

Mr. Hoxie also devotes a substantial portion of his reports to describing the prosecution history of the RE '984 Patent. Lee Decl., Ex. A, at ¶¶ 23–99; Ex. C, at ¶¶ 30–62. Rather than providing a straightforward summary, however, Mr. Hoxie offers his own characterization of the prosecution history events. For example, when describing Cipla's response to an office action,

[1] Mr. Hoxie also interprets the state of mind of Cipla's prosecuting attorneys, Cipla's employees, Cipla's inventors, and the patent examiner to support his legal conclusions. For example, in ¶ 39 of his Opening Report, [redacted] Lee Decl., Ex. A, at ¶ 39; *see also* Lee Decl., Ex. D, at 257:4–13.

Mr. Hoxie comments that [redacted] Lee Decl., Ex. A, at ¶¶ 77–78. Mr. Hoxie even offers a technical opinion, stating [redacted] Lee Decl., Ex. A, at ¶ 93.

B. Sunovion Expert Witness Ms. Samantha Miller

Sunovion expert witness Ms. Samantha Miller holds herself out as a "pharmaceutical executive specialized in business development and licensing. *See* Lee Decl., Ex. E, at ¶ 6. In her "20 years of experience" in that role, Ms. Miller testified that she has "negotiated [redacted] licensing deals" in the pharmaceutical industry. Lee Decl., Ex. F, at 12:20–25. In her report, Ms. Miller provides various opinions relating to the topic of royalty rates in patent licensing based on her own personal experience. *See generally* Lee Decl., Ex. E. For example (but not limited hereto), in her report, Ms. Miller provides the following opinions based exclusively (either explicitly or implicitly) on her own personal "experience":

- [redacted]
- [redacted]
- [redacted]
- [redacted]

At her deposition, Ms. Miller confirmed that the opinions in her report were based on her experience negotiating licensing deals in the pharmaceutical industry. *See, e.g.*, Lee Decl., Ex. F,

at 77:25–78:17, 85:15–22, 89:7–13. Ms. Miller conceded, however, that she had not disclosed any of the underlying facts related to those licensing deals, including the terms of the deals, because those facts are all "confidential." *See, e.g.*, *id.* at 77:25–11, 84:9–86:7, 86:14–87:3.

C. Sunovion Expert Witness Mr. Robert L. Vigil, Ph.D.

In an opening expert report, Cipla expert witness DeForest McDuff, Ph.D., provided his opinion on reasonable royalty damages suffered by Cipla as a result of infringement of the RE '984 by Sunovion. *See* Lee Decl., Ex. H ("McDuff Report"). Mr. McDuff evaluated and provided his opinion regarding [redacted].

On October 6, 2017, Sunovion expert witness Mr. Robert L. Vigil, Ph.D. submitted a "Rebuttal Expert Report" in response to the McDuff Report. *See* Lee Decl., Ex. I ("Vigil Report"). Therein, Mr. Vigil opined that Mr. McDuff incorrectly analyzed [redacted] *See* Vigil Report, at ¶¶ 81–98, & 110–118. The Vigil Report does not contain any discussion regarding [redacted].

At Mr. Vigil's deposition on November 17, 2017, Mr. Vigil sought to supplement his opinion based on a [redacted]." *See generally* Lee Decl., Ex. J, at 44:22–51:15. In particular, Mr. Vigil testified as follows (*id.* at 46:20–48:5):

[redacted]

[redacted]

Notably, Mr. Vigil conceded that neither [redacted] nor the information underlying his opinion regarding [redacted] was included in his report, [redacted] *Id.* at 46:18–19; 45:12–13, 48:11–49:21. In fact, [redacted] the day immediately before his deposition. *Id.* at 49:5-7.

D. Sunovion Expert Witness Dr. Leonard Chyall

In his expert report, Sunovion expert witness Dr. Leonard Chyall effectively concedes that Xopenex HFA and the [redacted] Authorized Generic fall within the literal words of the asserted claims, but nonetheless opines that the products "do not infringe the '984 patent pursuant to the reverse doctrine of equivalents." *See* Lee Decl., Ex. L ("Chyall Report"), at ¶¶ 61–91. Dr. Chyall opines that the products do not infringe pursuant to the reverse doctrine of equivalents because they [redacted] *See, e.g.*, Chyall Report, at ¶ 91. Dr. Chyall's overall opinion is premised on his conclusion that the asserted claims of the RE '984 Patent are directed to a *process*, and not the claimed product levalbuterol L-tartrate. For example, Dr. Chyall opines that [redacted] *Id.* at ¶ 83 (emphasis added).

RELEVANT LEGAL STANDARDS

A. *Daubert* and Federal Rule of Evidence 702

"The admissibility of expert testimony is governed by Federal Rule of Evidence 702." *Parallel Networks Licensing, LLC v. Int'l Bus. Machines Corp.*, No. CV 13-2072 (KAJ), 2017

WL 1405155, at *2 (D. Del. Apr. 17, 2017). Under Rule 702, "(1) the proffered witness must be an expert; (2) the expert must testify to scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact." *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, Civ. No. 11-515-LPS-CJB, 2015 WL 12815314, at *2 (D. Del. November 20, 2015) (citation omitted). Additionally, under Rule 702, "expert testimony is admissible only if it … is based on sufficient facts or data[,] ... is the product of reliable principles and methods [,] and ... reliably applie[s] the principles and methods to the facts of the case.'" Fed. R. Evid. 702.

"The role of the district court is to serve as a 'gatekeeper'—to protect the jury from evidence that is unreliable, confusing, or unduly prejudicial." *Parallel Networks*, 2017 WL 1405155, at *2; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589–92 (1993). In this role, the court should evaluate, *inter alia*, "whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability." Fed. R. Evid. 702, advisory committee notes, 2000 amendments (citing *Daubert*). "The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" *Id.*; *see, e.g.*, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.").

In line with these principles, opinions by legal experts on issues of law are inadmissible, and this court consistently excludes patent law experts from testifying with respect to patent law issues. *See AstraZeneca UK Ltd. v. Watson Labs., Inc.*, No. 10-915-LPS, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012); *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, No. 04-940-JJF, 2006 WL 2241018, at *1 (D. Del. Aug. 4, 2006). Furthermore, if the patent law expert seeks to testify on technical issues, the expert generally must also be qualified as a technical expert in the

pertinent art. *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1362 (Fed. Cir. 2008). Experts' summaries of patent prosecution history are also frequently excluded by this court. *See Ondeo Nalco Co. v. EKA Chemicals, Inc.*, No. 01-537-SLR, 2003 WL 1524658, at *3 (D. Del. Mar. 21, 2003); *Brigham & Women's Hosp. Inc. v. Teva Pharm. USA, Inc.*, No. CIV.A. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010).

B. Federal Rules of Civil Procedure

Federal Rule of Civil Procedure 26(a)(2)(B)(i) requires that expert reports contain "a complete statement of all opinions the witness will express and the basis and reasons for them[.]" Pursuant to Federal Rule of Civil Procedure 37(c)(1), "[i]f a party fails to provide information ... as required by Rule 26(a) ... the party is not allowed to use that information ... at a trial, unless the failure was substantially justified or is harmless." *See Pfizer Inc. v. Ranbaxy Labs. Ltd.*, No. CIV.A. 03-209-JJF, 2005 WL 3525681, at *2 (D. Del. Dec. 22, 2005). "Together, Rules 26 and 37 provide trial courts with discretion to exclude opinions that are not disclosed in expert reports." *Parallel Networks*, 2017 WL 1405155, at *1; *see Pfizer*, 2005 WL 3525681, at *2; *see, e.g.*, *Inline Connection Corp. v. AOL Time Warner Inc.*, 472 F. Supp. 2d 604, 614–15 (D. Del. 2007) (granting motion to exclude an opinion that was not disclosed in an expert report).

C. Adherence to the Court's Claim Construction

"[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). "Thus, once the court has conducted its claim construction, the parties may not contradict the court's construction to a jury." *PPC Broadband, Inc. v. Corning Gilbert Inc.*, No. 5:11-CV-761 GLS/DEP, 2014 WL 347800, at *3 (N.D.N.Y. Jan. 31, 2014). "Therefore, while experts may apply the court's claim construction and testify to the ultimate issue of infringement, they may not testify regarding claim construction." *Id.* (internal citations omitted).

ARGUMENT

I. Mr. Hoxie's Testimony Should be Excluded in its Entirety

Mr. Hoxie proffered testimony as a purported patent law expert on several substantive issues of patent law should be excluded. Mr. Hoxie devotes a large portion of his reports to opine on legal issues of recapture,[2] priority, original patent rule, error, prior user rights, and issues related to 35 U.S.C. § 102(g). *See, e.g.*, Lee Decl., Ex. A, at ¶¶ 100–128; Ex. B, at ¶¶ 11–18, 22–26, 35, 43, 45; Ex. C, at ¶¶ 10–29, 63–99; *see also* Appendix A. Mr. Hoxie's opinions amount to nothing more than a legal brief, and his testimony essentially adds another legal advocate on behalf of Sunovion. This alone is enough to exclude his entire testimony. *See AstraZeneca*, 2012 WL 6043266, at *1; *Procter & Gamble Co.*, 2006 WL 2241018, at *1. Mr. Hoxie's testimony provides no other benefit than an additional attorney argument and would waste trial time. The Court has extensive patent law experience, and a patent law expert is unnecessary. Mr. Hoxie's testimony should thus be excluded *outright*.

Mr. Hoxie's opinions on *technical* issues and documents should also be excluded. Mr. Hoxie is undisputedly not qualified as a POSA in this case, and he himself admits he is not [redacted] Lee Decl., Ex. D, at 165:19–166:24. Indeed, his bachelor's degree is in zoology. *Id.* at 161:20–162:24. Mr. Hoxie's testimony related to technical issues and technical documents in this case should thus be excluded. *See Sundance, Inc.*, 550 F.3d at 1362 ("Admitting testimony from a person … with no skill in the pertinent art, serves only to cause mischief and confuse the factfinder."). Mr. Hoxie is likewise not qualified to opine on FDA submission issues, and particularly their technical details to support his prior user rights opinions in his Rebuttal Report. *See Takeda Pharm. U.S.A., Inc. v. Par Pharm. Cos., Inc.*, No. 13-1524-

[2] Mr. Hoxie is further not qualified to testify with respect to recapture because he has only encountered the recapture rule [redacted] in his 30 years of experience in prosecuting patents, and characterizes it as a "[redacted]" Lee Decl., Ex. D, at 170:7–15; 170:22–171:2.

SLR (D. Del. Nov. 24, 2015). For similar reasons, Mr. Hoxie is not qualified to testify regarding the internal mechanisms of the Patent Office. Mr. Hoxie has never worked at the Patent Office, and can only speculate as to the interworking of the Office. Lee Decl., Ex. D, at 161:5–19.

Mr. Hoxie's opinions regarding invalidity and the state of mind of the examiner and applicants—which he presents in the *guise* of a prosecution history summary—should also be excluded. As noted above, this court often strikes patent law expert's testimony that simply "walks-through" prosecution history, particularly where they are laden with legal opinions and interpretations of the state of mind of an examiner or applicant. *See Ondeo Nalco Co.*, 2003 WL 1524658, at *3; *Brigham & Women's Hospital Inc.*, 2010 WL 3907490, at *2. Mr. Hoxie's so-called summary of the prosecution history here is intermingled with impermissible legal opinions on recapture and impermissible technical opinions on the disclosure of the specification, which should be excluded, as discussed above. *See, e.g.*, Lee Decl., Ex. A, at ¶¶ 45, 77–78, 93. Moreover, in his purported summary, Mr. Hoxie also speculates about the state of mind of the examiner, Cipla personnel, and Cipla's attorneys. This type of testimony is inappropriate. The Court should not allow expert testimony about "intent, motive, or state of mind, or evidence by such state of mind may be inferred." *AstraZeneca UK Ltd.*, 2012 WL 6043266, at*2.

II. Ms. Miller's Testimony Regarding Royalty Rates Should be Excluded

Ms. Miller's opinions relating to patent licensing royalty rates should be excluded pursuant to Federal Rule of Evidence 702. Ms. Miller's opinions are *not* "based on sufficient facts or data." Fed. R. Evid. 702. Rather, her opinions are based exclusively on her *personal experience* negotiating licensing deals in the pharmaceutically industry—none of which have been produced or otherwise provided in this case due to confidentiality obligations. *See, e.g.*, Lee

Decl., Ex. F, at 77:25–17, 84:9–86:7, 86:14–87:3.[3] Given the absence of sufficient facts underlying Ms. Miller's opinions, her opinions "cannot reasonably be assessed for reliability" or "challenged in some objective sense." Fed. R. Evid. 702, advisory committee notes, 2000 amendments. And the Court's gatekeeping function "requires more than simply 'taking the expert's word for it.'" *Id.* Ms. Miller's subjective opinions should thus be excluded as unreliable. *Id.*; *Daubert*, 43 F.3d at 1319 ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.").

Last night—on the literal eve of the deadline for *Daubert* Motions—Sunovion produced a document that appears to summarize, *at an extremely high level*, the various licensing agreements Ms. Miller has relied upon from her personal experience in rendering her opinions in this case. *See* Lee Decl., Ex. G. This summary document does not cure the defects in Ms. Miller's opinions, however. The licensing deals themselves Ms. Miller relies on have still not been produced. Thus, her opinions still "cannot reasonably be assessed for reliability" or "challenged in some objective sense, as required under Rule 702, even in view of this newly-produced summary of her creation. Despite the last minute production by Sunovion (which should be struck as untimely), the Court is still presented with nothing more than Ms. Miller's conclusions and assurances of reliability, which is plainly insufficient under *Daubert*.

III. Mr. Vigil's Testimony Regarding [redacted] Should be Excluded

As admitted by Mr. Vigil, his *new opinion* regarding [redacted] was *not included* in his expert report. *See, e.g.*, Lee Decl., Ex. J, at 46:18–19; 45:12–13, 48:11–49:21. As such, this new opinion may be excluded pursuant to

[3] In connection with Ms. Miller's opinion that [redacted] (Lee Decl., Ex. E, at ¶ 24), Ms. Miller does cite a *single* Cipla license agreement. *See* Lee Decl., Ex. E, at ¶ 27. But Ms. Miller plainly states that the Cipla agreement merely conforms to her opinion—it is not the basis for her opinion. *Id.*

Federal Rule of Civil Procedure 37(c)(1). *See Parallel Networks*, 2017 WL 1405155, at *1; *Inline*, 472 F. Supp. 2d at 614–15. Indeed, pursuant to Federal Rule of Civil Procedure 37(c)(1), Sunovion is not allowed to rely on this new opinion of Mr. Vigil unless the failure to include the opinion in his report was "substantially justified or is harmless."

No substantial justification exists for Mr. Vigil's failure to include this opinion in his report. For example, the opinion is not based on new, previously unavailable facts. Rather, Mr. Vigil testified that his new opinion was based [redacted]. *See, e.g.*, Lee Decl., Ex. J, at 44:22–51:15. Moreover, Mr. Vigil testified that he [redacted]" supporting this new opinion [redacted] but evidently did not see fit to further evaluate that evidence at that time [redacted] or otherwise). *See id.* at 47:4–6. That time, however, was the appropriate and required time to set forth any opinion on that evidence. *See* Fed. R. Civ. P. 26(a)(2)(B)(i).

Additionally, Mr. Vigil's failure to include this new opinion in his report is not harmless. Sunovion's corporate witness, Mr. Benjamin Enerson, previously testified under oath that [redacted] *See, e.g.*, Lee Decl., Ex. K, at 41:14–42:12. Cipla necessarily relied on that sworn testimony. Now, at the eleventh hour, however—and after the close of fact discovery—Sunovion effectively seeks to go back on that sworn testimony in self-serving fashion by presenting conclusory hearsay from Sunovion's internal litigation counsel that [redacted] Cipla's expert witness, Mr. McDuff, relied on in rending his initial opinion. This extremely late, material change to Sunovion's position in this case necessarily prejudices Cipla.

IV. Dr. Chyall's Testimony Should be Excluded in its Entirety

Dr. Chyall opines that, while the accused products in this case fall within the literal words of the asserted claims of the RE '984 Patent, the products nonetheless do not infringe pursuant to the *reverse* doctrine of equivalents. Lee Decl., Ex. L, at ¶¶ 61–91. "The reverse doctrine of equivalents is an equitable doctrine designed to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention." *Roche Palo Alto LLC v. Apotex, Inc.*, 531 F.3d 1372, 1377 (Fed. Cir. 2008). "Where a device is so far changed in principle from a patented article that it performs the same or similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the reverse doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement." *Id*. "[I]n determining whether the reverse doctrine of equivalents applies to preclude a finding of literal infringement, the Court must consider four criteria: (1) the principle of the claimed invention; (2) the principle of the accused product; (3) the degree of change in the principle of the accused product from that of the claimed invention; and (4) whether the accused product performs in a substantially different way." *Ciena Corp. v. Corvis Corp.*, 334 F. Supp. 2d 598, 604–605 (D. Del. 2004).[4]

Dr. Chyall's opinion regarding the reverse doctrine of equivalents is simply a restatement of a Sunovion claim construction position that the Court has previously *rejected*. In particular, during claim construction, the Court *rejected* Sunovion's proposed construction for "levalbuterol L-tartrate" and "(R)-salbutamol-(L)-tartrate salt" "that would read a process limitation into the claims." (D.I. 264, at 8–9). The Court also *rejected* Sunovion's proposed construction for "pure and isolated"—"A resolution intermediate that is converted to (R) salbutamol substantially free

[4] Overall, "[t]he reverse doctrine of equivalents is rarely applied," and the Federal Circuit "has never affirmed a finding of non-infringement under the reverse doctrine of equivalents." *Roche*, 531 F.3d at 1377; *accord DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1338 (Fed. Cir. 2009) ("[T]he doctrine is rarely invoked and virtually never sustained.")

of the (S) enantiomer that may further optically be converted to a pharmaceutically acceptable salt"—as it likewise impermissibly read a process limitation into the clams. (D.I. 264, at 9).

In spite of the Court's Markman Order, Dr. Chyall's opinion regarding the reverse doctrine of equivalents is premised on his conclusion that the asserted claims are directed to a *process*, as opposed to products alone. As noted above, "in determining whether the reverse doctrine of equivalents applies to preclude a finding of literal infringement," the Court must consider and evaluate "the principle of the claimed invention" as compared to the "principle of the accused product." *Ciena*, 334 F. Supp. 2d at 604–605. Dr. Chyall opines that [redacted] Lee Decl., Ex. L, at ¶ 83 (emphasis added). Dr. Chyall's foundational opinion regarding "the principle of the claimed invention" cannot be reconciled with the Court's claim construction, which rejected Sunovion's attempts to import such process limitations into the claims. (*See* D.I. 264, at 8–9). As such, Dr. Chyall's opinion regarding the reverse doctrine of equivalents should be excluded. *See PPC Broadband*, 2014 WL 347800, at *3.

CONCLUSION

For the foregoing reasons, Cipla respectfully requests that the Court exclude: Mr. Hoxie's testimony outright, as improper technical opinions and legal conclusions; Ms. Miller's testimony relating to patent licensing royalty rates, pursuant to Federal Rule of Evidence 702; Mr. Vigil's *new* opinion regarding [redacted], pursuant to Federal Rule of Civil Procedure 37(c)(1); and Dr. Chyall's opinion with respect to the reverse doctrine of equivalents, as a contradiction to the Court's claim construction.

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APPENDIX A

Legal Issue	Examples of Objectionable Testimony by Mr. Hoxie
Priority	[redacted] (Lee Decl., Ex. A, Opening Report ¶ 102; *see also* ¶¶ 25–30, 101, 124; Lee Decl.,Ex. C, Reply Report ¶¶ 65–66.)
Original Patent Rule	[redacted] (Lee Decl., Ex. D, Hoxie Dep. Tr. 208:20–209:11 (Nov. 14, 2017); *see also* Lee Decl., Ex. A, Opening Report ¶¶ 105–111, 125–126; Lee Decl., Ex. C, Reply Report ¶¶ 31, 48, 54, 67–72.)
Error Requirement	[redacted] (Lee Decl., Ex. A, Opening Report ¶ 116; *see also* ¶¶ 39, 112–115, 127; Lee Decl., Ex. C, Reply Report ¶¶ 31, 52, 55, 58, 63–64, 73–87.)
Recapture Rule	[redacted] (Lee Decl.,Ex. A, Opening Report ¶ 123.) [redacted] (Lee Decl.,Ex. D, Hoxie Dep. Tr. 36:7–39:2 (Nov. 14, 2017) (discussing *Atlantic Thermoplastics, Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992)); *see also* Lee Decl., Ex. A, Opening Report ¶¶ 77–78, 100, 117–123, 128; Lee Decl.,Ex. C, Reply Report ¶¶ 34, 40–42, 51, 54, 56–57, 60, 88–96.)

Legal Issue	Examples of Objectionable Testimony by Mr. Hoxie
35 U.S.C. § 102(g)	[redacted] (Lee Decl., Ex. C, Reply Report ¶ 27, *see also* ¶¶ 10–26, 28–29.)
Prior User Rights	[redacted] (Lee Decl., Ex. B, Rebuttal Report ¶ 22, *see also* ¶¶ 7, 9, 11–18, 23–26, 29, 35, 43–45.)